

EXHIBIT 22

**Memorandum**

Date **JAN 3 | 1997**

From June Gibbs Brown
Inspector General *June G Brown*

Subject Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services

To (A-06-95-00064)

Bruce C. Vladeck
Administrator
Health Care Financing Administration

Attached for your information and use is our final report entitled, "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the District of Columbia Department of Human Services." This review was conducted as part of a nationwide audit of pharmacy drug acquisition costs at the Health Care Financing Administration's request. Most States reimburse pharmacies for Medicaid prescriptions using a formula which generally discounts the average wholesale price (AWP) by 10.5 percent. The objective of our review was focused on developing an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

The District of Columbia Department of Human Services (District) was 1 of 11 States randomly selected as part of the nationwide review. District of Columbia reported drug expenditures of \$28.3 million in Calendar Year 1994.

Through statistical sampling, we obtained pricing information from 13 District of Columbia pharmacies. We obtained 343 invoice prices for brand name drugs, and 156 invoice prices for generic drugs. The overall estimate of the extent that AWP exceeded pharmacy purchase invoice prices was 17.3 percent for brand name drugs and 43.8 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. The estimates combine the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain, and urban-independent pharmacies. The estimates exclude the results obtained from non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, home IV, etc.) because such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inappropriately inflated our percentages.

We are recommending that the District consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs.

Page 2 - Bruce C. Vladeck

In response to our draft report, the Commissioner of the District Commission of Health Care Finance had some concerns about the report, but stated that the District would consider the results of our review when contemplating future Medicaid Drugs. The complete text of the Director's comments are included in Appendix 4.

We welcome any comments you have on this report. If you have any questions, call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410)786-7104.

To facilitate identification, please refer to Common Identification Number A-06-95-00064.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF PHARMACY ACQUISITION COSTS
FOR DRUGS REIMBURSED UNDER THE
MEDICAID PRESCRIPTION DRUG PROGRAM
OF THE
DISTRICT OF COLUMBIA DEPARTMENT OF
HUMAN SERVICES**



JUNE GIBBS BROWN
Inspector General

JANUARY 1997
A-06-95-00064

SUMMARY

At the request of the Health Care Financing Administration (HCFA), the Office of Inspector General (OIG) conducted a nationwide review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program. Since most States reimburse pharmacies for Medicaid prescriptions using a formula which discounts the average wholesale price (AWP), the objective of our review was to develop an estimate of the discount below AWP at which pharmacies purchase brand name and generic drugs.

To accomplish our objective, we selected a random sample of 11 States from a universe of 48 States and the District of Columbia. Arizona was excluded from the universe of States because the Medicaid drug program is a demonstration project using prepaid capitation financing and Tennessee was excluded because of a waiver received to implement a statewide managed care program for Medicaid. The District of Columbia was one of the sample States selected, as well as California, Delaware, Florida, Maryland, Missouri, Montana, Nebraska, New Jersey, North Carolina, and Virginia.

Additionally, we selected a sample of Medicaid pharmacy providers from each State and obtained invoices of their drug purchases. The pharmacies were selected from each of five categories--rural-chain, rural-independent, urban-chain, urban-independent and non-traditional pharmacies (nursing home pharmacies, hospital pharmacies, etc.). We included the non-traditional category so as to be able to exclude those pharmacies from our overall estimates. We believed such pharmacies purchase drugs at substantially greater discounts than retail pharmacies, and including them would have inflated our percentages.

We compared each invoice drug price to AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. We then projected those differences to the universe of pharmacies in each category for each State and calculated an overall estimate for each State. Additionally, we projected the results from each State to estimate the nationwide difference between AWP and invoice price for each category.

In the District of Columbia, we obtained pricing information from 13 District of Columbia pharmacies. Specifically, we obtained 343 invoice prices for brand name drugs, and 156 invoice prices for generic drugs. For the District of Columbia, the overall estimate of the extent that invoice prices were discounted below AWP was 17.3 percent for brand name drugs and 43.8 percent for generic drugs. The national estimates are 18.3 percent and 42.5 percent, respectively. The national estimates combine the results for four categories of pharmacies including rural-chain, rural-independent, urban-chain and urban-independent. The District of Columbia estimates do not include any rural categories as the District has no rural areas. The estimates exclude the results obtained from non-traditional pharmacies.

We are recommending that the District of Columbia Department of Human Services (District) consider the results of this review as a factor in any future changes to pharmacy reimbursement for Medicaid drugs. We will share the information with HCFA from all 11 States in a consolidation report for their use in evaluating the overall Medicaid drug program.

The Commissioner of the District Commission of Health Care Financing responded to our draft report in a letter dated November 26, 1996. While the Commissioner had some concerns about the report, he stated that the District would consider the results of our review when contemplating future changes to the pharmacy reimbursement for Medicaid drugs. The complete text of the Commissioner's comments are included in Appendix 4.

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INTRODUCTION

At the request of HCFA, OIG, Office of Audit Services (OAS) conducted a review of pharmacy acquisition costs for drugs reimbursed under the Medicaid prescription drug program of the District of Columbia Department of Human Services (District). The objective of our review was to develop an estimate of the difference between the actual acquisition costs of drugs and AWP. This review was conducted as a part of a nationwide review of pharmacy acquisition costs. The District of Columbia was 1 of 11 States randomly selected as part of the nationwide review.

BACKGROUND

Medicaid regulations provide for the reimbursement of drugs using two methods. If a drug is a multiple source (generic) drug, then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or an upper limit amount plus a dispensing fee. The Federal upper limit amounts are established by HCFA. If a drug is a single source (brand name) drug, or a generic drug for which an upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost (EAC) plus a reasonable dispensing fee. The State agencies are responsible for determining the EAC and the dispensing fee.

The EAC for most States is calculated by using AWP for a drug less some percentage. The AWP is the price assigned to the drug by its manufacturer and is listed in either the *Red Book*, *Medispan* or the *Blue Book*--publications universally used in the pharmaceutical industry. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs. However, OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP. In 1989, OIG issued a follow-up report which concluded that pharmacies were purchasing drugs at discounts of 15.5 percent below AWP. Both the 1984 and 1989 reports combined brand name and generic drugs in calculating the percentage discounts and included a comparison of 3,469 and 4,723 purchases, respectively.

In 1989, HCFA issued a revision to the State Medicaid Manual which pointed out that a preponderance of evidence demonstrated that AWP overstated prices that pharmacies actually paid for drugs by as much as 10 to 20 percent. The Manual further provided that, absent valid documentation to the contrary, it would not be acceptable for a State to make reimbursements using AWP without a significant discount.

In November 1990, the Omnibus Budget Reconciliation Act of 1990 was passed which placed a 4-year moratorium on changes to States' reimbursement policies. The moratorium expired on December 31, 1994 and HCFA requested that we, once again, determine the difference between AWP and actual pharmacy acquisition cost.

The District reported drug expenditures of \$28.3 million in Calendar Year (CY) 1994.

SCOPE

Our review was performed in accordance with generally accepted government auditing standards. The objective of our review was to develop an estimate of the difference between AWP and the actual invoice prices of both brand name and generic prescription drugs to Medicaid pharmacy providers. Our objective did not require that we identify or review any internal control systems.

Our review was limited to ingredient acquisition costs and did not address other areas such as: the effect of Medicaid business as a contribution to other store sales; the cost to provide professional services other than dispensing a prescription such as therapeutic interventions, patient education, and physician consultation; and the cost of dispensing which includes costs for computers, multi-part labels, containers, technical staff, transaction fees, Medicaid specific administrative costs, and general overhead. We also did not take into consideration the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations. We plan to evaluate the effect of the Federal upper limit amounts on generic drug reimbursements in a subsequent review.

We obtained a listing of all Medicaid pharmacy providers from the District. The District was responsible for classifying each pharmacy as chain, independent or non-traditional. For purposes of this review, a chain was defined as four or more pharmacies with common ownership. We determined whether each pharmacy was rural or urban by comparing the county location for each pharmacy to a December 31, 1992 listing of metropolitan areas and their components. The District of Columbia had no rural areas. We selected a stratified random sample of 12 pharmacies from each of 3 strata--urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). The non-traditional category contained only three pharmacies and we selected all of those pharmacies. We included the non-traditional category so as to be able to exclude those pharmacies from our estimates. We believed that such pharmacies are able to purchase drugs at substantially greater discounts than a retail pharmacy and would inflate our estimate. The nationwide review included two more strata--rural-chain and rural-independent.

We requested, from each pharmacy selected, the largest invoice from each different source of supply for a specified month in CY 1994. We identified the sources of supply as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. Each pharmacy was initially assigned a month from January through September in order to provide a cross-section of this 9-month time period. However, we permitted some pharmacies to provide invoices from October as invoices were not available from the earlier period.

We reviewed every line item on the invoices supplied by the sample pharmacies to ensure that the invoices contained the information necessary for our review. We eliminated over-the-counter items. Some invoices did not include National Drug Codes (NDC), which were needed to obtain AWP for the drug. We attempted to obtain NDCs in those instances. We used the 1994 *Red Book*, a nationally recognized reference for drug product and pricing information, to obtain NDCs or identify over-the-counter items. One prominent wholesaler, whose invoices contained that wholesaler's item number rather than NDCs, provided us with a listing that converted their item number to an NDC. If we were unable to identify the NDC for a drug, we eliminated the drug. This was a common occurrence for generic drugs where there was no indication on the invoice as to the manufacturer of the drug.

We obtained a listing from HCFA that indicated whether a drug is a brand name or generic drug. We used that listing to classify each drug on the invoices as brand or generic. If a drug was not on the HCFA listing, we used the *Red Book* to determine whether the drug was brand or generic. Additionally, we obtained drug expenditure information from HCFA-64 Reports.

The State of Missouri provided us with a pricing file for the purpose of obtaining the AWP for each drug. We compared the invoice drug price to AWP for each drug and calculated the percentage, if any, by which the invoice price was discounted below AWP. If a drug from an invoice was not on the pricing file we eliminated that drug.

An initial meeting was held in Richmond, Virginia on August 30 - 31, 1994, with Medicaid pharmacy representatives from the sample States. At this meeting, we presented a methodology for performing the review and the methodology was refined with input from the State representatives. At a follow-up meeting held in Richmond, Virginia, on September 27 - 28, 1995, we presented the results of our review with the sample States.

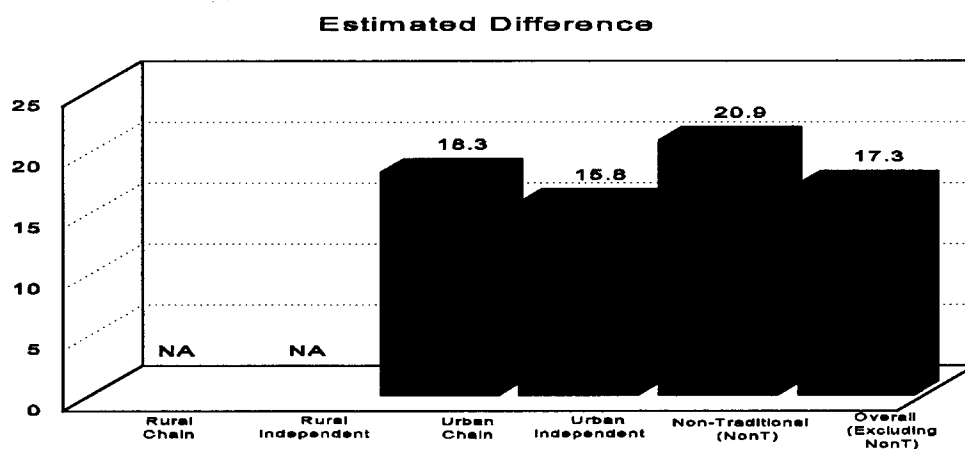
We used OAS statistical computer software to calculate all estimates as well as to generate all random numbers. We did not independently verify any information obtained from third party sources. Our review was conducted by our Little Rock, Arkansas OAS field office with assistance from our OAS field offices in Baton Rouge, Louisiana, and Austin, Texas from September 1994 to September 1995.

FINDINGS AND RECOMMENDATIONS

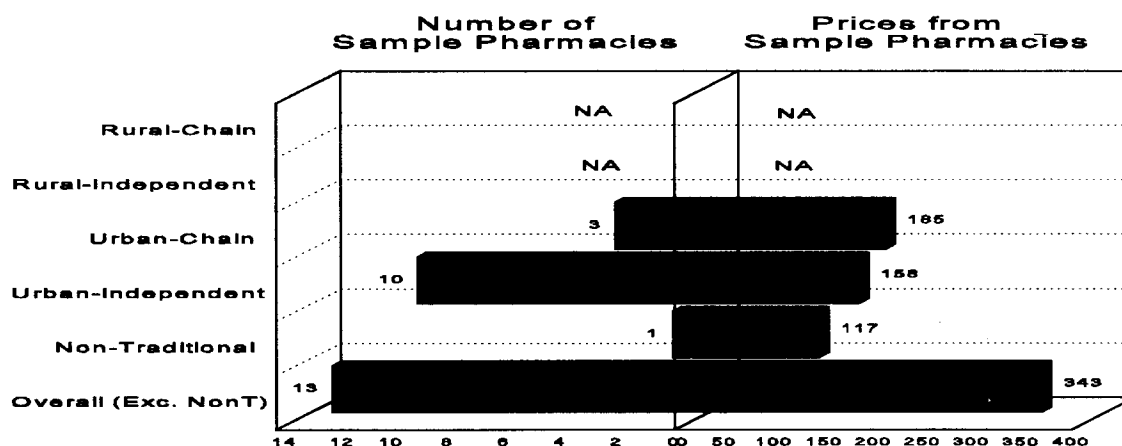
BRAND NAME DRUGS

We estimate that invoice prices for *brand name drugs* were discounted 17.3 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 343 invoice prices received from 13 pharmacies. The standard deviation for this estimate was 1.28 percent (see Appendix 2).

The estimates of the discount below AWP of invoice prices for *brand name drugs* are summarized in the following graph:



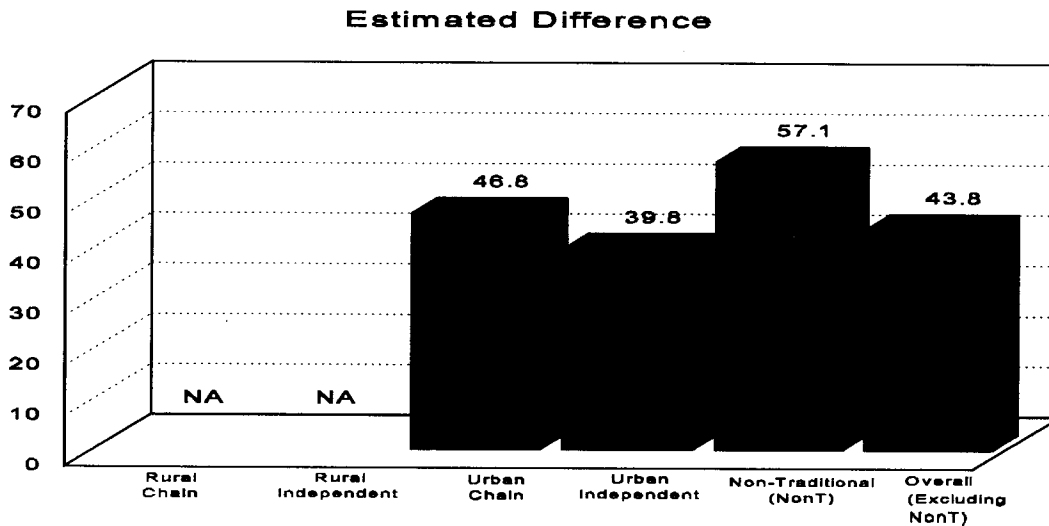
The following graph shows the number of pharmacies sampled and the number of prices reviewed by individual category for *brand name drugs*.



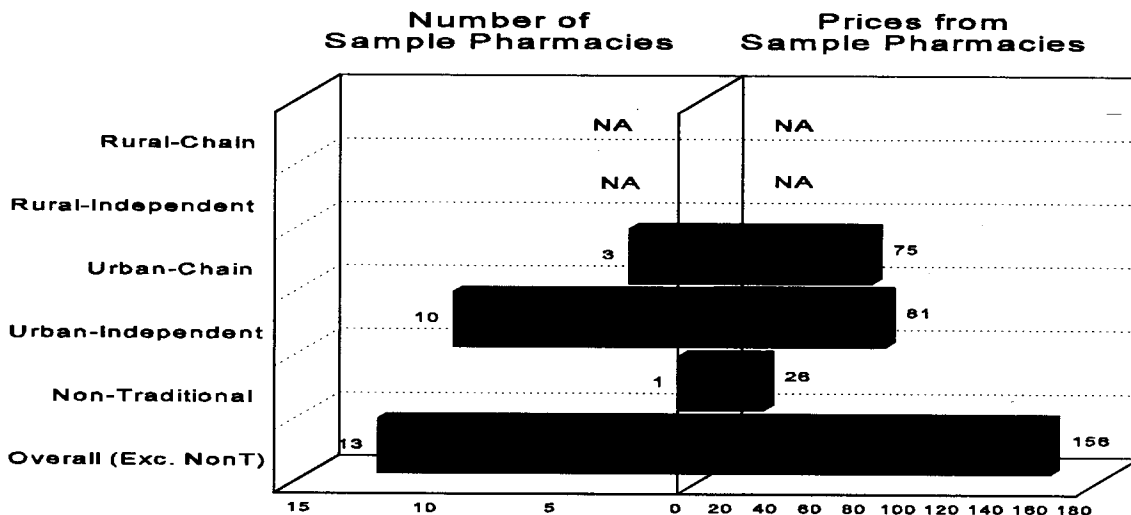
GENERIC DRUGS

We estimate that invoice prices for *generic drugs* were discounted 43.8 percent below AWP. Once again the estimate combined all pharmacy categories except non-traditional pharmacies. The estimate was based on the comparison to AWP of 156 invoice prices received from 13 pharmacies. The standard deviation for this estimate was 1.74 percent (see Appendix 2).

The estimates of the discount below AWP of invoice prices for *generic drugs* are summarized by individual categories in the following graph:



The following graph shows the number of pharmacies sampled and the number of prices reviewed by individual category for the *generic drugs*.



CONCLUSIONS AND RECOMMENDATION

Based on our review, we have determined that there is a significant difference between AWP and pharmacy acquisition costs. The difference between AWP and pharmacy acquisition costs is significantly greater for generic drugs than for brand name drugs. In general, State representatives believed that the review supported current State practices to establish pharmacy reimbursement for ingredient cost at levels below AWP.

We recognize that acquisition cost is just one factor in pharmacy reimbursement policy and that any change to that policy should also consider the other factors discussed in the Scope section of our report. Additionally, the effect of Federal upper limit amounts on generic drug reimbursements or usual and customary charge limitations should be taken into consideration. However, a change in any of the factors affecting pharmacy reimbursement could have a significant impact on expenditures because of the size of the program (\$28.3 million) in the District of Columbia. We believe that the difference between AWP and pharmacy acquisition costs as determined by our review is significant enough to warrant consideration by the State in any evaluation of the drug program. Therefore, we recommend that the District consider the results of this review in determining any future changes to pharmacy reimbursement for Medicaid drugs.

STATE AGENCY COMMENTS

The Commissioner of the District Commission of Health Care Financing responded to our draft report in a letter dated November 26, 1996. While the Commissioner had some concerns about the report, he stated that the District would consider the results of our review when contemplating future changes to the pharmacy reimbursement for Medicaid drugs. Specifically, the Commissioner expressed concern that (1) the District sample was too small, (2) the Federal upper limits were not considered for this study, (3) the conversion of invoice "item" numbers to NDCs was inadequately explained in relation to other States' wholesalers, and (4) the elimination of generic drugs without NDCs made it unclear as to which generic drugs provided the basis for our conclusion. The complete text of the Commissioner's comments are included in Appendix 4.

OIG RESPONSE

The primary objective of our review was to develop a nationwide estimate of the discount below AWP at which Medicaid pharmacies purchased prescription drugs. The nationwide projections are based on over 28,000 invoice prices obtained from 315 pharmacies. We provided reports on the individual State results as a courtesy to the participating States.

We agree the Federal upper limits have a significant impact on reimbursement to Medicaid pharmacies. As we stated in the Scope Section of our report, we plan to evaluate the effect of Federal upper limit amounts on generic drugs in a subsequent review. However, Federal upper limits have no impact on what pharmacies pay for drugs and as such would have no relationship to our audit objective.

We stated in the Scope Section of our report that one wholesaler provided us with a listing that converted their item numbers to NDCs. We did not state that we used that wholesalers information to convert any other wholesalers item numbers, but rather we stated that we used the 1994 **Red Book** to obtain NDCs.

The nationwide estimate of the discount below AWP at which Medicaid pharmacies purchase generic drugs is based on the comparison of 9,075 invoice prices to AWP. These 9,075 prices would have come from invoices that identified the NDC or from invoices that we were able to identify the NDC.

APPENDICES

APPENDIX 1
PAGE 1 of 2

SAMPLE DESCRIPTION

Sample Objectives:

Develop an estimate of the discount below Average Wholesale Prices (AWP) of actual invoice prices to Medicaid pharmacies in District of Columbia for brand name drugs and for generic drugs.

Population:

The sampling population was pharmacy providers participating in the Medicaid prescription drug program of the District.

Sampling Frame:

The sampling frame was a listing of all pharmacy providers participating in the Medicaid prescription drug program.

Sample Design:

A sample of 12 pharmacies was to be selected from each of 5 strata. The five strata of pharmacies were rural-chain, rural-independent, urban-chain, urban-independent, and non-traditional (nursing home pharmacies, hospital pharmacies, home IV, etc.). The District of Columbia had no rural areas so the two rural strata were eliminated. The non-traditional category contained only three pharmacies and we selected all of those pharmacies. Each pharmacy was assigned a month from 1994 for which to provide invoices. All pharmacies were initially assigned a month from January through September in a method designed to provide a cross-section of the 9-month period. However, some pharmacies were permitted to submit invoices from October as invoices were not available for the month originally assigned. The largest invoice from each of four different sources of supply was requested. The sources of supply were identified as wholesalers, chain warehouse distribution centers, generic distributors, and direct manufacturer purchases. All invoice prices were compared to AWP.

APPENDIX 1
PAGE 2 of 2

Sample Size:

Thirteen pharmacies were selected from each of the 2 urban strata and 1 pharmacy was selected from the non-traditional stratum for a total of 14 pharmacies.

Source of Random Numbers:

OAS statistical sampling software was used to generate the random numbers.

Characteristics to be Measured:

From our review of the pharmacy invoices, we calculated the percentage of the discount below AWP of actual invoice prices for all drugs on the invoices submitted.

Treatment of Missing Sample Items:

No spare was substituted for a pharmacy that did not provide information. If a pharmacy did not send an invoice for a particular type of supplier, we assumed that the pharmacy did not purchase drugs from that type of supplier during the month assigned to the pharmacy.

Estimation Methodology:

We used OAS Statistical Software to project the percentage of the discount below AWP of actual invoice prices for each stratum, as well as an overall percentage difference. The overall percentage difference excluded the non-traditional pharmacies. The projections were done separately for brand name drugs and generics.

Other Evidence:

We obtained AWP from First DataBank.

APPENDIX 2

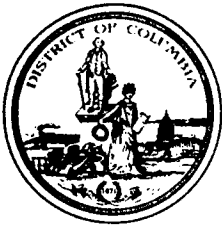
**DISTRICT OF COLUMBIA SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS**

RURAL-CHAIN	NA	NA	NA	NA	NA	NA	NA
RURAL-INDEPENDENT	NA	NA	NA	NA	NA	NA	NA
URBAN-CHAIN	74	3	185	18.3	3.86	14.75	21.92
URBAN-INDEPENDENT	56	10	158	15.8	2.60	14.61	17.07
NON-TRADITIONAL	3	1	117	20.9	0.00	20.90	20.90
OVERALL (EXCL. NON-TRAD)	130	13	343	17.3	1.28	15.15	19.37
RURAL-CHAIN	NA	NA	NA	NA	NA	NA	NA
RURAL-INDEPENDENT	NA	NA	NA	NA	NA	NA	NA
URBAN-CHAIN	74	3	75	46.8	0.81	46.08	47.59
URBAN-INDEPENDENT	56	10	81	39.8	13.97	33.20	46.38
NON-TRADITIONAL	3	1	26	57.1	0.00	57.10	57.10
OVERALL (EXCL. NON-TRAD)	130	13	156	43.8	1.74	40.93	46.67

APPENDIX 3

**NATIONWIDE SAMPLE RESULTS
BRAND NAME AND GENERIC DRUGS**

RURAL-CHAIN	1,095	73	5,723	17.40	1.05	15.67	19.13	
RURAL-INDEPENDENT	1,499	78	3,043	16.39	1.07	14.63	18.15	
URBAN-CHAIN	8,194	73	7,198	18.45	0.52	17.60	19.31	
URBAN-INDEPENDENT	6,242	91	3,009	18.71	0.90	17.22	20.19	
NON-TRADITIONAL	2,026	66	1,762	27.52	2.28	23.76	31.27	
OVERALL (EXCL. NON-TRAD)	17,030	315	18,973	18.30	0.66	17.21	19.38	
RURAL-CHAIN	1,095	73	2,963	47.51	1.63	44.82	50.20	
RURAL-INDEPENDENT	1,499	78	1,798	47.38	0.93	45.85	48.92	
URBAN-CHAIN	8,194	72	2,634	37.61	2.82	32.97	42.26	
URBAN-INDEPENDENT	6,242	91	1,680	46.72	2.44	42.70	50.73	
NON-TRADITIONAL	2,026	59	1,262	57.70	1.98	54.43	60.96	
OVERALL (EXCL. NON-TRAD)	17,030	314	9,075	42.45	0.90	40.97	43.93	



GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HUMAN SERVICES
WASHINGTON, D.C. 20002

NOV 26 1996

IN REPLY REFER TO:

Commission on Health Care Finance
2100 Martin Luther King Avenue, S.E.
Suite 302
Washington, D.C. 20020

George M. Reeb
Assistant Inspector General for
Health Care Financing Audits
N2-25-26
7500 Security Boulevard
Baltimore, Md. 21244-1850

Dear Mr. Reeb:

The District of Columbia Commission on Health Care Finance acknowledges receipt of the draft report on pharmacy acquisition costs for drugs reimbursed under the D.C. Medicaid Pharmacy Program. As you stated in your introductory letter, this review was initiated to develop an estimate of the difference between the actual acquisition costs of drugs at the pharmacies and average wholesale price (AWP) for both brand name and generic drugs.

Your report reviewed the original Health Care Financing Administration's (HCFA) aforementioned request and the methodology chosen to satisfy that request.

As a result of our participation in the current study, several program criteria were acknowledged as impacting the data. A major concern was the quantity of pharmacies in the sample. Out of about 300 pharmacy providers participating in the D.C. Medicaid Prescription Drug Program, 14 sent back invoices (10 independent, 3 chain and 1 non-traditional pharmacy). Only 13 pharmacies were used in making the calculations. Wholesaler invoices were sent to the Office of the Inspector General (OIG) for comparisons to the State of Missouri's pricing file for the purpose of obtaining the AWP for each drug. I am concerned about the size of the sample in relation to the total pharmacies requested to forward information.

GEORGE M. REEB

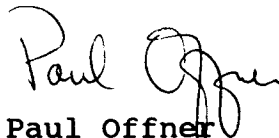
PAGE TWO

Additional concerns relate to the report's "SCOPE" section. They are the following:

- o The Federal Upper Limits were not taken into consideration for this study. This has an impact on pricing, as HCFA adopted a federal upper limit (FUL) ceiling price for certain multiple source drugs based on the application of a specific formula. A multiple source drug is a drug marketed or sold by two or more manufacturers or labelers. This pricing methodology is based on the least costly therapeutic equivalent. It would definitely reduce the reimbursement rate by State Medicaid Programs, as these prices would supersede the AWP based pricing rate for generic medications.
- o The OIG converted invoice "item" or catalog numbers to National Drug Codes (NDCs). This was accomplished by using a wholesaler's provider listing. The report states a prominent wholesaler was used. However, the conversion methodology and its relationship to other states' wholesalers are not identified.
- o If the OIG was unable to identify the NDC, the drug was eliminated from the review. This was a common occurrence for generic drugs which had no identification on the wholesaler's invoice as to the manufacturer. As a result, it is not clear which generic drugs provided the basis for the conclusion that the AWP exceeded invoice prices for generic drugs by 43.8 per cent in the District of Columbia.

Given these concerns, the Commission has some misgivings as to the weight that should be attached to this report. Nevertheless, we will take it into account when contemplating future changes to pharmacy reimbursement for Medicaid drugs.

Sincerely,


Paul Offner
Commissioner

cc: Wayne Casey, Interim Director, DHS
Donna Bovell, Pharmacy Consultant,
CHCF